

- **ABOUT THIS REPORT**

- PharmaVitae Explorer database

- **EXECUTIVE SUMMARY**

- Catalysts

- **PDUFA DATES**

- Regeneron
 - Zaltrap: PDUFA – August 4
 - Eylea: PDUFA – September 21
- Salix
 - Crofelemer: PDUFA – September 5
- Ironwood
 - Linaclotide: PDUFA – September 8
 - Linaclotide clinical trials
- NPS Pharmaceuticals
 - Gattex PDUFA – September 28
 - Gattex should win approval based on positive Phase III data and CHMP positive opinion
- Amylin
 - Metreleptin: PDUFA – October 3
 - Ultra-rare nature of lipodystrophy lowers bar for approval
- Santarus
 - Uceris: PDUFA – October 16
 - Uceris clinical trials
- United Therapeutics
 - Oral treprostinil: PDUFA – October 26
- Medivation
 - Enzalutamide: PDUFA – November 21
- Onyx
 - Regorafenib: PDUFA – November 23
 - Positive data make approval likely, but uptake may be low
- Exelixis
 - Cabozantinib: PDUFA – November 29
 - Cabozantinib looks likely to be approved based on strong Phase III data

- **PHASE III TRIAL RESULTS**

- ArQule: tivantinib – non-small cell lung cancer
 - Tivantinib: Phase III results – H2 2012
 - Interim analysis of MARQUEE trial expected in H2 2012
- BioMarin: Firdapse – Lambert-Eaton myasthenic syndrome
 - Firdapse Phase III results – H2 2012
 - Phase III LMS-002 trial
- BioMarin: GALNS – mucopolysaccharidosis IVA

- GALNS Phase III results – H2 2012
- Phase II trials
- Phase III trial
- Elan: bapineuzumab – Alzheimer’s disease
 - Bapineuzumab Phase III results – H2 2012
 - Phase II trials
 - Phase III trials
- Rigel: fostamatinib – rheumatoid arthritis
 - Fostamatinib Phase III results – H2 2012
 - Phase III program: OSKIRA and head-to-head clinical trials

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